DETAILED ACTION

This Office Action is a response to Applicant's Preliminary Amendment filed June 22, 2006.

Claims 3-6, 8-12, 14, 17-20, 22-26, 28, 30-45, and 47-53 have been canceled. Claims 2, 7, 14, 15, 16, 21, 27, 29, 46, and 54 have been amended.

Claims 1, 2, 7, 13, 15, 16, 21, 27, 29, 46, and 54 are pending in the instant application.

Claims 1, 2, 7, 13, 15, 16, 21, 27, 29, 46, and 54 are subject to restriction as detailed below:

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 2 and 16, drawn to a method for inducing apoptosis in a cell comprising reducing expression or activity of one or more mitotic checkpoint molecules, wherein the expression of the one or more mitotic checkpoint molecules is reduced by contacting cells with a siRNA specific for BubR1, Mad2, Bub3 or CENP-E. This group is subject to a further species election as detailed below.

Group II, claim(s) 7 and 21, drawn to a method for inducing apoptosis in a cell comprising reducing expression or activity of one or more mitotic checkpoint molecules, wherein the expression of the one or more mitotic checkpoint molecules is reduced by contacting cells with an antibody that binds BubR1, Mad2, Bub3 or CENP-E. This group is subject to a further species election as detailed below.

Group III, claim(s) 46 and 54, drawn to a composition comprising a therapeutically effective amount of a siRNA specific for a mitotic checkpoint molecule, wherein the mitotic checkpoint molecule is BubR1, Mad2, Bub3 or CENP-E. This group is subject to a further species election as detailed below.

Claim 1, 13, 15, 27, and 29 link(s) inventions I and II. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1, 13, 15, 27, and 29 for Groups I and II. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim,

such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The groups of inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Groups I and II lack unity of invention because even though the inventions of these groups require the technical feature of a method for inducing apoptosis in a cell comprising reducing expression or activity of one or more mitotic checkpoint molecules, wherein the expression of the one or more mitotic checkpoint molecules is reduced, this technical feature is not a special technical feature as it does not make a contribution over the prior art in view of Chan et al. (of record cited on International Search Report mailed June 22, 2006) or Gorbsky et al. (of record cited on International Search Report mailed June 22, 2006). Chan et al. disclose a method for inducing apoptosis in a cell comprising administering an antibody that reduces the expression or activity of a mitotic checkpoint molecule, wherein the antibody is BubR1 or Bub3. Gorbsky et al. disclose a method for inducing apoptosis in a cell comprising administering an antibody that reduces the expression or activity of a mitotic checkpoint molecule, wherein the antibody is Mad2. Thus, the special technical feature does not make a contribution over

the prior art and the groups lack unity of invention. Furthermore, the prior art destroys any special technical feature that might link the inventions.

The inventions listed as Groups II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no apparent special technical feature that links the inventions. Group II appears to be based on a method for inducing apoptosis in a cell comprising reducing expression or activity of one or more mitotic checkpoint molecules, wherein the expression of the one or more mitotic checkpoint molecules is reduced by contacting cells with an antibody that binds BubR1, Mad2, Bub3 or CENP-E. However, Group III is based on a composition comprising a therapeutically effective amount of a siRNA specific for a mitotic checkpoint molecule, wherein the mitotic checkpoint molecule is BubR1, Mad2, Bub3 or CENP-E. There is no apparent special technical feature that links the inventions.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Claims 2 and 16 are drawn to patentably distinct methods of using siRNA specific for BubR1, Mad2, Bub3 or CENP-E and one must be selected.

Claims 7 and 21 are drawn to patentably distinct methods of using mitotic checkpoint antibodies that binds BubR1, Mad2, Bub3 or CENP-E and one must be selected.

Claims 46 and 54 are drawn to patentably distinct mitotic checkpoint siRNA specific for BubR1, Mad2, Bub3 or CENP-E and one must be selected.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each mitotic checkpoint molecule represents a different gene where each is a different structure/sequence where the activity between each gene varies and the level of activity of one gene cannot predict the level of activity of another. Each gene requires a different search and analysis. The search of each individual gene is required where there is not one search that will provide discernable results for each the genes recited in the claims.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise require all the limitations of an allowed generic claim. Currently, the following claim(s) are generic: 1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement

may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are 3subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached Monday thru Friday between 9-5 pm.

If attempts to reach the examiner by telephone are unsuccessful please contact Fereydoun Sajjadi at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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/Terra Cotta Gibbs/
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